

# EXHIBT 2

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	TAN, Barrie
App. No.	:	10/821,679
Filed	:	April 8, 2004
For	:	Annatto Extract Compositions, including Geranyl Geraniols and Methods of Use
Examiner	:	Meller, Michael V.
Group Art Unit	:	1655

**DECLARATION UNDER 37 C.F.R. §1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. I, BARRIE TAN, a citizen of the United States, hereby declare that:

2. My address is 49 Northhampton Road, Amherst, MA, 01002

3. I am the inventor of the invention in U.S. Application Serial No. 10/821,679 entitled "Annatto Extract Compositions, including Geranyl Geraniols and Methods of Use" (the "Application") filed April 8, 2004.

4. I have over 25 years experience in Chemistry, Biochemistry, and Nutrition. I received my Ph.D. in Chemistry at the University of Otago/New Zealand in 1978 and completed 2.5 years of post-Doctoral work in Biochemistry at Auburn University/Alabama (1979-1981). I have been conducting research in tocotrienols and tocopherols for more than 20 years.

5. I understand that the Examiner has rejected Claims 5-7, 30, 32-34, 40, and 41 35 USC 102(b) as being anticipated by Alaux et al., Levy et al., Kapadia et al. or JP 2001114628. The Examiner has stated that Alaux, Levy, and Kapadia each teach an annatto extract and JP teaches an oral agent containing an agent from *Bixa orellana*, thus it also teaches an annatto extract.

6. I have read each of the cited references and they do not disclose the composition as claimed in the present application. The references disclose an annatto extract that contains bixins or other colorants.

7. The disclosed composition in the application is distilled from the byproduct solution of *Bixa orellana* seed components. The byproduct solution of *Bixa orellana* seed components is obtained after removing the bixins to produce “yellow cake” and has greatly reduced levels of bixins.

8. The phrase “annatto extract” as used in the references pertains to extracts with bixins, which are not included in the “annatto extract” as used in the present application.

9. The disclosed geranyl geraniols in the application are obtained from the 290 – 390 Dalton MW fraction of the byproduct solution of *Bixa orellana* seed components.

10. A person having ordinary skill in the arts would recognize that geranyl geraniols are 290 Daltons in molecular weight and Bixins are 390 - 425 Daltons in molecular weight. These molecular weights are easy to calculate from the structures of these chemicals. Additionally, their chemical structures show that geranyl geraniols have 1 oxygen groups and bixins have 4 oxygen groups

11. A person having ordinary skill in the arts would recognize that the higher the number of oxygen groups a molecule contains, the less likely it is to distill. Geranyl geraniol has 1 oxygen group, tocotrienols and tocopherols have 2 oxygen groups, bixins have 4 oxygen groups; and triglycerides have 6 oxygen groups. Therefore, geranyl geraniol distills before the tocotrienols and tocopherols, and bixins and triglycerides remain in the residue.

12. Also, a person having ordinary skill in the arts would be able to calculate the molecular weights of the isomers of tocopherol and tocotrienol from their chemical structures as: Alpha-Tocopherol = 430, Beta-Tocopherol = 417, Gamma-Tocopherol = 417, Delta-Tocopherol = 403, Alpha-Tocotrienol = 424, Beta-Tocotrienol = 411, Gamma-Tocotrienol = 410, and Delta-Tocotrienol = 396.

13. I am the inventor of Tan et al. (US 6,350,453). A person having ordinary skill in the arts would recognize that the conditions (e.g. temperature) during the distillation process to obtain the 290 – 390 Dalton MW fraction of the byproduct solution of *Bixa orellana* seed components would effect the trans-to-cis isomer ratio in the fraction.

14. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. Moreover, these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

January 5, 2007  
Date

/Barrie Tan/  
Barrie Tan